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| 09/553,573      | 04/19/2000  | Gary K. Michelson M.D. | 101.0077-00000      | 3776             |

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MARTIN & FERRARO, LLP  
1557 LAKE O'PINES STREET, NE  
HARTVILLE, OH 44632

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| EXAMINER |
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SNOW, BRUCE EDWARD

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| ART UNIT | PAPER NUMBER |
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3738

DATE MAILED: 01/20/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/553,573

Applicant(s)

MICHELSON M.D., GARY K.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34,36-42 and 101-155 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34,36-42 and 101-155 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings were received on 11/20/03. These drawings are accepted by the Examiner.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "facing side walls" and "inner surface facing each other".

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore the following must be shown or the feature(s) canceled from the claim(s). No new matter should be entered:

- 1) "facing side walls" and "inner surface facing each other" are not shown.
- 2) The hollowing interior as claimed is not shown.
- 3) Claim 2, "first distance is greater than the third".

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The amendment filed 9/11/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material

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which is not supported by the original disclosure is as follows: The new limitation added to page 17, line 6, describing the opposed portions of the implant can be in a moveable relationship is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 (and duplicates) rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The embodiments taught in this application do not have opposed portions which are moveable to adjust angulation of adjacent vertebral bodies. This claim limitation is not enabled. It is noted that the current application is a 09/553000 which does not even support this limitation.

Claims 1 and its dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Regarding claim 1, the limitation, "*said hollow interior having a maximum dimension.. maximum dimension of said opening*" is not supported in the original specification. Note that the elected embodiment shown in figures 5-6 teaches the implant is solid between the openings. See the cross-section in figure 6.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the limitations, "said interior surface and exterior facing side walls having an inner surface facing each other" (cancelled claim 35) and "*said hollow interior having a maximum dimension.. maximum dimension of said opening*" is not understood. Similar for all independent claims.

Claims 8 and 9 are not understood. Same for claims 105-106. Please explain. Applicant's explanation is appreciated, however, the limitation is still not understood. Please diagram.

Claim 39, moveable relationship is not understood.

**Include claims 102-155 corresponding with the above claims in the rejection.**

Claim 147, "interior side wall" lacks antecedent basis.

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Claim 147, what is the disc space?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 147-151, 153 are rejected under 35 U.S.C. 102(b) as being anticipated by Albert (FR 2724312).

Referring to figure 1, Albert teaches a spinal implant having a width approximately  $\frac{1}{2}$  of the maximum width of the vertebral into which it is intended to be implanted. The implant has a first distance that is greater than a second distance and a third distance greater than said second distance. See attachment of Figure 2 with the Examiner's interpretation.

The implant inherently has opposed portions which maintain a desired height of two adjacent vertebrae. The implant is interpreted as having one large opening in each opposed portion fulfilling the claim language "*said opposed portions having at least one opening therein.*"

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The implant is fully capable of being used with a spine to fulfilling the functional language of claim 147.

Claims 102-155 are rejected under 35 U.S.C. 102(b) as being anticipated Kozak et al (5,397,364).

Kozak et al teaches a spinal implant having a width approximately  $\frac{1}{2}$  of the maximum width of the vertebral into which it is intended to be implanted; see element 30, figure 6. The implant has a first distance that is greater than a second distance and a third distance greater than said second distance. Kozak et al teaches the implant having a leading end and a trailing end adapted to rest upon portions of the apophyseal rim; see column 5, lines 35-59.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 152 is rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (FR 2703580) in view of Michelson (5,609,635).

Albert discloses the spinal implant as described in the rejections above.

However, Albert is unclear to the fusion promoting materials used therewith. Michelson

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teaches different materials, configurations, etc. used with a spinal implant. It would have been obvious to one having ordinary skill in the art to have utilized the roughened surfaces, fillings, or coatings, etc. as taught by Michelson, or known in the spinal art, to enhance fusion between the implant and vertebrae.

Note Michelson, teaches angular relationship of the upper and lower surfaces.

Regarding claim 34, note that Michelson teaches a more extensive opposing surfaces with more than two openings. It would have been obvious to one having ordinary skill in the art to have used the more extensive openings of Michelson with the implant of Albert to distribute more weight.

Claims 1-34, 36-42, and 101-155 (all claims) are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Kuntz (4,349,921).

Referring to figures 1-17, Michelson teaches a spinal implant having an anterior aspect, a posterior aspect, and sidewalls. Michelson further teaches opposed surfaces having at least one opening and said opposed surfaces can be relatively angled. Michelson further teaches all claimed surfaces, elements, and material. However, Michelson does not teach the implant being less than approximately one-half the maximum width of the adjacent vertebrae.

Kuntz teaches a spinal implant can be formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6. It would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of



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Michelson because "*when a prosthesis for the lumbar area is required, it has been found advantages to make the prosthesis in two halves.*" see column 9, lines 41 **et seq.**

In dividing the implant in two halves, it would have been obvious to one having ordinary skill in the art that in some embodiments, interior walls would be formed for structural integrity.

Note figures 12-14 of Kuntz teaching moveable opposing surfaces.

***Response to Arguments***

Applicant's arguments filed 7/24/03 have been fully considered.

Regarding at least claim 39, the Examiner's position is fully described in the grounds of rejection above.

Regarding the previous rejection of claim 35 under 35 U.S.C. 112, second paragraph "Claim 35, "hollow interior" is ambiguous as to the intended element. Please direct to the figures and specification for support", applicant states, page 19, "[f]or claim 35, Applicant addressed this rejection and cancelled claim 35.." The limitations of claim 35 are now in independent claim 1 and are still unclear.

Regarding the combination rejections in view of Michelson in view of Kuntz, applicant is arguing that Michelson does not have a third distance along an interior side wall. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re*

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*Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Kuntz reference clearly teaches the advantage of an implant comprising two halves. See the rejection above. Regarding the disadvantages of having a porous implant, this is an extraneous teaching of Kuntz which is not relying upon in the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs:

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes

A handwritten signature in black ink, appearing to be 'BS' with a long horizontal stroke extending to the right.

BRUCE SNOW  
PRIMARY EXAMINER